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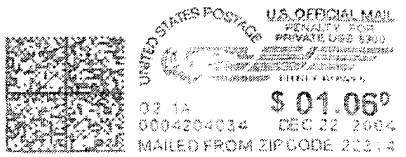

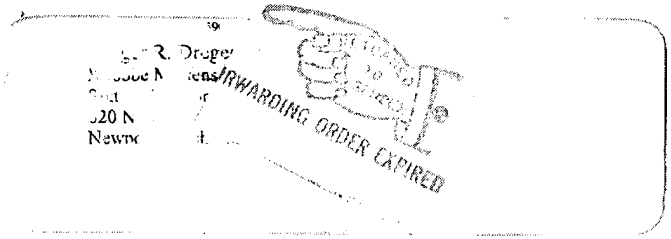

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,387	12/12/2001	Kevin P. Baker	GNE.2830P1C54	9861

7590 12/22/2004

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,387	BAKER ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35, 38-40 and 44-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33-35 and 38-40* is/are allowed.

6)☒ Claim(s) *28-32 and 44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. The rejections of claims 28-47 under 35 U.S.C. 101 because the claimed invention lacks patentable utility is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112 – Scope of Enablement

2. The rejection of claims 28-47 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 112 – Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 28-32 and 44-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification, since the claims are not limited to any particular SEQ ID NO, but are open to a nucleic acid that ranges from 80% to 99% identical to SEQ ID NO: 219, without any guidance on conserved portions of the protein structure. Further, the claims encompass "hybridization" language without any correlative function as required by the utility guidelines.

Most significantly, the genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No 219. Thus, applicant has express possession of only one particular nucleic acid sequence in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains.

There is no showing or evidence which links structural limitations or requirements to any particular functional limitations. Further, these claims encompass alternately spliced versions of the nucleic acids, allelic variants including insertions and mutations, nucleic acids which encode inactive precursor proteins which have a removable amino terminal end, and only specific nucleic and amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nucleic acids as having 80%-99% sequence identity to SEQ ID NO: 219 lacks any specific structure, since it lacks the correlation between structure and function that is at the heart of the caselaw and of the written description guidelines.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound without identifying the structure function relationship of the compound, so that the compound is claimed solely its

nucleic acid sequence related 80%-99% to SEQ ID NO: 219 without any correlative function to delimit the structure.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO 219. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

5. The rejection of claims 41-43 under 35 U.S.C. 102(b) is moot in view of the cancellation of those claims.

Allowable Subject Matter

6. Claims 33-35 and 38-40 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: Claims 33-35 and 38-40 are drawn to a specific sequence which has the utility of inducing B-cell precursors to proliferate, which may be useful in the treatment of diabetes. These claims are described and there is no prior art which teaches or suggests the specifically claimed sequence.

Response to Arguments

8. Applicant's arguments filed November 8, 2004 have been fully considered but they are not persuasive.

Written Description rejection

The first issue is whether the claims comply with the written description requirement of 35 U.S.C. 112, first paragraph. In this analysis, Applicant attempts to address the structure function issue by adding the function "wherein the encoded polypeptide induces proliferation of kidney mesangial cells". This function has literally nothing to do with structure whatsoever. Appellant also fails to note that a "representative number of species" is required. This is considered by the USPTO written description guidelines which note that in an unpredictable art, a single species is not sufficient to describe the genus.

It is the absence of any real structure function relationship and the absence of a representative number of species which supports the conclusion that there is insufficient descriptive support for the current claims. This argument rests on several grounds. First, the single sequence that is actually described is not representative of the genus of any sequence which hybridizes under the stated conditions. Second, the claims entirely lack a structure function relationship since the function given has no ability to limit the genus of polypeptides. Third, the claim encompasses species other than human.

Absence of a representative number of species

In the current case, the first question is what constitutes a generic claim. The genus of polypeptides represents every possible variation which could occur in SEQ ID

Nos: 220, that has 80% identity. For the 603 nucleotides which encode this protein of 201 amino acids, 20% variation permits a change of 120 nucleotides. In order to provide a representative number of species, in a genus which contains literally 4^{120} (or written out fully, approximately 176,684,706,477,838,430,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000) different members, the court in Lilly required "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. (Lilly at page 1406)." (As a side comment, the genus size here is larger than that at issue in Deuel). Lilly continues to note that in other cases, two chemical compounds in a subgenus were insufficient to describe that genus. In the current case, Appellant argues that the single species of a single SEQ ID NO is sufficient to describe 4^{120} other sequences for which no description whatsoever is given. These sequences may be of any size or structure, so long as they are 80% identical. Applicant's analysis is flawed since there is no expectation in the instant case of insubstantial variation because the functional limitation devolves solely to the ability of the protein to induce proliferation of kidney mesangial cells. However, this induction is entirely unrelated to the structure of the protein. The function provides absolutely no guidance or information regarding the structure and does not delimit the structure in even the smallest or most miniscule possible way. So the argument by Applicant that there would be insubstantial variation is not correct since the function of overexpression

does not limit the protein in any significant way.

Applicant appears to also be making the argument that the size of the genus is not relevant. This is not found persuasive because the size of the genus is a central issue. If the genus were small, a written description rejection would be less likely, since the examples would be more representative of the genus. Here, where the genus includes 176,684,706,477,838,430,000,000,000,000,000,000,000,000,000,000,000,000,000,000, 000,000,000,000 different members, none of which are disclosed or taught by Applicant, the argument that the demonstrated species is representative is not found persuasive.

Absence of any structure-function relationship

Second, when Applicant relies upon the analysis of the written description guidelines, this analysis is based upon the assumption that there will be insubstantial variation, as noted in many of the examples including example 9. However, Applicant's analysis is flawed since there is no expectation in the instant case of insubstantial variation because the functional limitation devolves solely to the ability of the protein to induce proliferation of kidney mesangial cells. This is not like example 9, where the functional limitation involved a protein which retained adenylate cyclase activity. In the example 9 case, the argument of insubstantial variation was that there was an expectation that stringently hybridizing proteins which retained the specific function of stimulating adenylate cyclase would differ insubstantially. Applicant's fundamental position fails to equate with the written description guidelines because in the guidelines,

there is function correlated to the structure. The function in Applicant's claims, however, lack any association with the structure of the protein whatsoever. So consonant with the case law in Lilly, Enzo and the other written description decision of the Federal Circuit, it is clear that the current claims fail to meet the written description requirement because there is no structure function relationship which limits the genus size. The guidelines require more. They require a structure function relationship.

The claim scope broadly encompasses sequences from other species

Finally, when Applicant argues that the case is different from the issues cited in Lilly and Fiers, Applicant fails to appreciate the breadth of the claim. The current claim clearly reads on sequences found not only in humans, but in other species. This was the crux of the decision in Lilly, that a rat insulin sequence did not provide sufficient breadth to provide descriptive support for a claim which encompassed human insulin nucleic acid sequences. Applicant's claim suffers from the same flaw, since the claim would clearly encompass sequences from other species. For example, an alignment of nucleotides 103-942 of SEQ ID NO: 219 with the mouse Genbank Accession No. NM 175631 shows an 81% alignment (with one region having an 89% alignment). (This is post filing date art). So the claim as written would encompass an mouse sequence, not described by Applicant, which is the express problem raised in Lilly. It is clear that Applicant did not have possession of this sequence, since there was no recognition of the particular changes that would result in the sequence. (see alignment below).

>gi|28274689|ref|NM_175631.1| Mus musculus cerebellin 4 precursor protein (Cbln4), mRNA
Length = 2802

Score = 628 bits (317), Expect = e-176
Identities = 485/541 (81%)
Strand = Plus / Plus

```
Query: 103  gttctgcatgagctccttaaaggacaaaggtaacagagccagcgagagagctcgagggga 162
            ||||||||||||||||||||||||||||||||||||||||||||||||| ||  || |||| ||||
Sbjct: 937  gttctgcatgagctccttaaaggacaaaggtaacagagccagccagccagttcgaaggga 996


Query: 163  gactttgacttcaagccacagaattggtggaagtgtgcgcgccgccgccgccgtcgc--- 219
            |||      ||||  ||  ||||||||||||||| |||||||| || |||| |||
Sbjct: 997  gac------ttcagtcctgagaattggtggaagtgcgcgcgccgctgctgccgccgccac 1050


Query: 220  ------tcctgcagcgctgtcgacctagccgctagcatcttcccgagcaccgggatcccg 273
                 |||||||||||||||| |||||| || || |||||||||| || ||||||||
Sbjct: 1051 cgctgttcctgcagcgctgtcgatctagccactggcgtcttcccgagctcccggatcccg 1110


Query: 274  gggtaggaggcgacgcgggcgagcaccagcgccagccggctgcggc-tgcccacacggct 332
            |||||| ||||| ||| | |||||  |||||||   |||||| || ||| ||| |||||
Sbjct: 1111 gggtagcaggcgccgcctgggagcagaagcgcca---ggctgccgcttgcgcacgcggct 1167


Query: 333  caccatgggctccgggcgccgggcgctgtccgcggtgccggccgtgctgctg 384
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Sbjct: 1168 caccatgggctccgcgcgccgggcgctgtccgtggtaccagccgttctgctg 1219


Query: 402  gctgcccgtctgggcacagaacgacacggagcccatcgtgctggagggcaagtgtctggt 461
            |||||| |||||||||||||| |||||||| || ||||| ||||||||||||||||||
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Query: 462  ggtgtgcgactcgaacccggccacggactccaagggctcctcttcctccccgctggggat 521
            |||||||||||||||||| || || |||||||||| || || || ||||| ||||||||
Sbjct: 1288 ggtgtgcgactcgaacccagctacagactccaagggatcatcatcttcccctctggggat 1347


Query: 522  atcggtccgggcggccaactccaaggtcgccttctcggcggtgcggagcaccaaccacga 581
            |||||||||||| || |||||||||| || || |||||||| ||||||||||||||||
Sbjct: 1348 atcggtccgggcagcaaactccaaggtggcttttcggcggttcggagcaccaaccacga 1407


Query: 582  gccatccgagatgagcaacaagacgcgcatcatttacttcgatcagatcctggtgaatgt 641
            |||||| ||||||||||||||||| |||||||||||||| |||||||||||||| || ||
Sbjct: 1408 gccatctgagatgagcaacaagactcgcatcatttacttttgatcagatcctggttaacgt 1467


Query: 642  gggtaatttttttcacattggagtctgtctttgtagcaccaagaaaaggaatttacagttt 701
            |||||||||||||||||||| |||||||||| ||||| || |||||||| || |||||
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Query: 702  cagttttcacgtgattaaagtctaccagagccaaactatccaggttaacttgatgttaaa 761
            |||||||||||| |||||||||||||||||||||| ||||||||||||||||||||||
Sbjct: 1528 cagttttcacgtaattaaagtctaccagagccaaaccatccaggttaacttgatgttaaa 1587


Query: 762  tggaaaaccagtaatatctgcctttgcgggggacaaagatgttactcgtgaagctgccac 821
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Sbjct: 1588 tggaaaaccagtcatctctgcatttgctggtgataaagatgtgacccgtgaagccgccac 1647


Query: 822  gaatggtgtcctgctctacctagataaagaggataaggtttacctaaaactggagaaagg 881
             ||||| || || || ||||| || ||||| |||||||| ||||||||||||||||||||
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Sbjct: 1708 taacttgctcggtggctggcagtattccacgttttctggctttctggtgtttcctctata 1767

Query: 942  g 942
             |
Sbjct: 1768 g 1768
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So the claims clearly encompass sequences which were neither taught nor described by the current specification. The claims include a single species which is not representative of the full scope of the genus. The guidelines support the rejection, particularly the requirement of Example 9 for a structure function relationship. Therefore, the written description rejection is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
12/17/09

INFORMATION DISCLOSURE STATEMENT PTO-1449	ATTY. DOCKET NO.: 39780-2830 P1C54	SERIAL NO.: 10/015,387
	APPLICANT : Kevin P. BAKER, et al.	
	FILING DATE: December 12, 2001	GROUP: 1637

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE

FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
						☐	☐

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	Ahlgren, Ulf, et al., "β-Cell-specific inactivation of the mouse *Ipf1/Pdx1* gene results in loss of the β-Cell phenotype and maturity onset diabetes", Genes & Development, Vol. 12, pp. 1763-1768, 1998.
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	Ono, Takahiko, et al., "Broad Antiproliferative Effects of Benidipine on Cultured Human Mesangial Cells in Cell Cycle Phases", American Journal of Nephrology", Vol. 22, pp 581-586, 2002.
✓	Ruef, Christian, et al., "Interleukin 6 is an autocrine growth factor for mesangial cells", Kidney International, Vol. 38, pp 249-257, 1990.
✓	Striker, Liliane J., et al., "The Contribution of Glomerular Mesangial Cells to Progressive Glomerulosclerosis", Seminars in Nephrology, Vol. 9, No. 4, pp 318-328, December 1989.

EXAMINER ✓	DATE CONSIDERED 11/17/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT PTO-1449	ATTY. DOCKET NO.: 39780-2830 P1C54	SERIAL NO.: 10/015,387
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FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
						☐	☐

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓	Wolf, Gunter, et al., "Angiotensin II Stimulates the Proliferation and Biosynthesis of Type 1 Collagen in Cultured Murine Mesangial Cells", American Journal of Pathology, Vol 140, No. 1, January 1992.
✓	Zalzman, Michal, et al., "Reversal of hyperglycemia in mice by using human expandable insulin-producing cells differentiated from fetal liver progenitor cells", PNAS, Vol. 100, No. 12, June 10, 2003.

EXAMINER ✓	DATE CONSIDERED 12/9/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.